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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/559,577

12/05/2005

Youichi Kyuuko

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EXAMINER

SAUCIER, SANDRA E

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

06/25/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/559,577	<b>Applicant(s)</b> KYUUKO ET AL.	
	<b>Examiner</b> Sandra Saucier	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/28/08</u> .                                                 | 6) <input type="checkbox"/> Other: _____                          |

#### DETAILED ACTION

Claims 1-12 are pending and are considered on the merits. Applicants' species election of 6-hydroxy-2,5,7,8,-tetramethylchroman 2-carboxylic acid is acknowledged.

#### ***Election/Restriction***

Applicant's election of the species, with traverse, of 6-hydroxy-2,5,7,8,-tetramethylchroman 2-carboxylic acid in the reply filed on 4/25/08 is acknowledged. The traversal is on the ground that all compounds possess a special technical feature in a common chroman structure. This is not found persuasive because 1) a special technical feature is a feature not found in the prior art, see MPEP § 1.475 and the chroman structure is well known in the prior art, thus it cannot be a special technical feature by definition. Second, each chroman structure requires mutually exclusive characteristics as outlined in the office requirement of 3/35/08 on page 3. Third, burden is not a consideration for Rule 371 applications. The lack of unity rules apply, which have no requirements concerning burden or lack thereof.

The requirement is still deemed proper and is therefore made FINAL.

#### ***Information Disclosure Statement***

The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search

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Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

***Claim Rejections – 35 USC § 112***

**INDEFINITE**

Claims 1–12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of the independent claim states that it is a method for producing an optically active chromancarboxylate; however, no production of an optically active ester is in the body of the claim.

Claim 11 is not interpretable. Is it the acid or the ester which is recovered/separated. Also, there is no antecedent basis for the recitation of “the optically active chromancarboxylate”.

Claim 12 lacks antecedent basis for the recitation of “ the optically active chromancarboxylate”, and also this step would result in the reversal of the enantiomeric esterification, i.e. the racemic substrate of formula (1) would result without a separation of the acid and ester prior to hydrolysis. Also, this step does not further limit the stated intent of the method in the preamble which is a method of producing an optically active chromancarboxylate.

Claims 1–12 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, see MPEP § 2172.01. The omitted steps are: recovery or separation of the optically active chromancarboxylate.

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The claims are incomplete in the absence of a recovery/separation step for the product produced.

It is clear from the record and would be expected from conventional preparation processes that the product must be isolated from the acid. Thus, the claims fail to claim the "Complete" process since the recovery/separation step is missing from the claims. The metes and bounds of the claimed process are therefore not clearly established or delineated.

### ***Claim Rejections – 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1–12 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2003–144190 [N] in combination with Kircher *et al.* [U].

The claims are directed to an enantiomeric esterification of the compound of formula (1), elected species of 6-hydroxy-2,5,7,8-tetramethyl chromancarboxylic acid using a biocatalyst, specifically lipase from the genus *Candida*.

JP 2003–144190 describes an enantiomeric separation of the stereoisomers of (R,S) 6-hydroxy-2,5,7,8-tetramethyl chroman-2-carboxylic acid esters by stereoselectively hydrolyzing the S-ester using *Candida antarctica* lipase. Particularly preferred are alkyl esters with 1–4 carbons. The

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reference lacks the use of the reverse reaction, esterification to separate enantiomers of the compound.

Kirchner *et al.* disclose that enantiomers may be separated by hydrolysis or esterification in organic solvents. The advantages of the use of the esterification reaction instead of the hydrolysis reaction are (i) there is not need to convert an alcohol or an acid to an ester prior to the enzymatic resolution, thereby eliminating one synthetic step; (ii) stability of enzymes is much greater in organic solvents than in water, etc. page 7075, second column.

Thus, the reversal of the enantiomeric scheme from the stereoselective hydrolysis of a racemic acid ester employed in JP 2003-144190 to an enantioselective esterification of the racemic acid as described in Kirchner *et al.* for the advantages described would have been obvious.

With regard to claim 12, one of skill in the art can hydrolyze the ester group from the enantiomerically purified acid ester if desired by simple base treatment.

One of ordinary skill in the art would have been motivated at the time of invention to make this substitution in order to obtain the resulting compound as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

### ***Conclusion***

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). It is applicants' burden to indicate how amendments are supported by the ORIGINAL disclosure. Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sandra Saucier/  
Primary Examiner  
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